



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,605	08/31/1999	CHRISTOPHER G. TAYLOR	38-21-(15757	1594
27161	7590	10/20/2005	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/386,605

Applicant(s)

TAYLOR ET AL.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 11 April 2005,.
2. Applicant has requested canceling claims 3, 4, and 7, and amending claims 1 and 8. Claims 1, 5, and 8-11 are pending, and are examined in the instant action.
3. Claim 5 is listed as being dependent on claim 4, which is a canceled claim. In order to expedite prosecution, the Office assumes that claim 5 is dependent on claim 1. Applicant must clarify this claim in response to this action.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

6. From the previous action: Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed (60/098,402) fails to provide adequate support under 35 U.S.C. 112 for claims 1, 3-5, and 7-11 of this application. Accordingly, Applicant shall have benefit of the date of filing of the non-provisional Application, 31 August 1999.

Since the claimed method is directed toward subject matter not disclosed in the provisional application, Applicant shall have priority benefit of the date of filing of the non-provisional application, 31 August 1999.

Art Unit: 1638

Applicant traverses saying primarily (Response, p. 5) that enablement and written description support are found in the provisional application, and requests specific details.

Applicant's traversal is unpersuasive. Specifically lacking support are: *the hypocotyl explant having a cut end below the cotyledon* (claim 1, line 4) and *to produce the chimeric dicot plant having transformed roots and wild-type shoots stems and leaves* (claim 1, lines 9 and 10). See provisional application p.40.

Applicant shall have priority benefit of the date of filing of the non-provisional application, 31 August 1999.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, and 5, 8-11, dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The rejected subject matter is "cotton". Applicant is invited to point out the page and line number in the specification where "cotton" can be found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

Art Unit: 1638

9. The claim 5 rejection under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 5 is the method of claim 1 where in the *Agrobacterium rhizogenes* is strain K599. The specification lacks sufficient evidence that the claimed biological material is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 CFR 1.801-1.809. If the claimed biological material was deposited under the provisions of the Budapest treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the grant of the patent. Applicant's attention is directed to 37 CFR § 1.801-1.809, MPEP § 2402-2411.05 and In re Lundak 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulation for Deposit of Biological Materials for Patent Purposes.

Since the *Agrobacterium Rhizogenes* strain K599 does not appear to be commercially available, this rejection is maintained.

10. Claims 1, 5, and 8-11 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for soybean hypocotyls and potato branches, does not reasonably provide enablement for any explant of any plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

Art Unit: 1638

nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's claims are broadly drawn to any explant of any plant.

Re any explant:

Applicant teaches soybean hypocotyls and potato branches. Hypocotyls and stems are not representative of all explants. Stems and hypocotyls are explants which have undergone differentiation and possess special features such as hormone gradients (Raven et al, Biology of Plants (1992), Worth Publishers, New York, NY 10003, pages 548). These explants (stem & hypocotyls) "know which end is up". Not all explants have these features. It is unpredictable that other explants not having these features, would be capable of functioning in the same way as stems and hypocotyls in the claimed invention. Neither the prior art nor Applicant's disclosure shows that explants other than stems and hypocotyls are capable of functioning as desired in the claimed invention. Accordingly, it is unpredictable that explants other than stems and hypocotyls can be used to practice the claimed invention as commensurate in scope with the claims.

Re any plant:

Applicant claims any plant. Applicant teaches soybean and potato, which are dicot plants. Dicot plants are not representative of all plants. Especially they are not representative of monocot plants. The properties of stems of dicot plants differ from those of monocot plants (Raven et al, Biology of Plants (1992), Worth Publishers, New York, NY 10003, pages 382, Table 18, and 494-5, Figures 23-8, 23-9 and 23-10). Dicots

Art Unit: 1638

show secondary growth, characterized by the presence of secondary meristematic tissue. Dicot stem cells have the capacity to dedifferentiate and become meristematic, whereas monocot stems cells do not have this capacity. It is unpredictable that plants other than dicots would be capable of functioning in the same way as the dicots in the claimed invention. Neither the prior art nor Applicant's disclosure shows that plants other than dicots are capable of functioning as desired in the claimed invention. Accordingly, it is unpredictable that plants other than dicots can be used to practice the claimed invention as commensurate in scope with the claims.

In view of the breadth of the claims (any explant and any plant) and the lack of guidance in the specification, undue experimentation would be required to enable the invention as commensurate in scope with the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tulson et al (EP 0262972 A2 published April 6, 1988), in view of Simpson et. al.

Art Unit: 1638

(1986) Plant Mol. Biol. vol 6, pages 403-415 and Savka et. al. (1990) Phytopathology vol 80, pages 503-508.

Tulson teaches a method of producing a stably transformed chimeric cucumber having transgenic root tissue. Tulson et al teach obtaining an hypocotyl explant (page 5, lines 30-40), inoculating with *Agrobacterium rhizogenes* (page 5, lines 52-55), culturing (page 5, lines 52-55), and producing plants (page 6, lines 1-15). Tulson teaches obtaining an explant (page 5, lines 30-40) where the explant is a hypocotyl with the cut end below the cotyledon. Tulson teaches the cut end of the hypocotyl being contacted with *Agrobacterium rhizogenes* (page 5, lines 52-55). Tulson teaches placing the inoculated hypocotyl on a medium containing MS (page 6, lines 4-6). Applicant is reminded that use of $\frac{1}{4}$ MS is indefinite as discussed above and thereby is given no weight in this discussion. Tulson teaches placing the inoculated hypocotyl on a medium containing MS and a selectable agent. (Page 6, lines 7 and 8). Tulson teaches using kanamycin wherein the concentration of kanamycin in the media is 25 mg/L (page 7, lines 22-28), which is less than 50 mg/l.

Applicant defines a "chimeric plant" (specification., p. 4) as a plant having only a portion of its cells transgenic. Tulson's original plant material (p. 5, lines 52-60) was a wild-type green cucumber seedling which had been inverted, cut at the hypocotyl , the cut end inoculated with *Agrobacterium rhizogenes*, and the inoculated end allowed to root. Tulson (p. 6, lines 45-55) harvested 690 roots from *Agrobacterium rhizogenes*-inoculated hypocotyl sections. Of these roots, 64 regenerated plantlets, 22 of which were positive for NPTII, the transgenic selection marker. Of the regenerated plantlets

Art Unit: 1638

(11) which had never been selected for NPTII expression using kanamycin selective growth conditions, two plantlets were positive for NPTII, as determined by the in vitro assay. Since these two plants had never been selected on kanamycin, the mother roots from which they came were transgenic for NPTII. However the mother plant (hypocotyl + stem + other green parts) was otherwise wild-type, since only newly growing roots would have been transformed. The protein encoded by the NPTII gene confers kanamycin resistance to plants expressing this gene. Cucumber is a dicotyledonous plant.

Tulson does not teach soybean, cotton or potato, or the use of *Agrobacterium Rhizogenes* strain K599.

Simpson et. al. (1986) *Plant Mol. Biol.* vol 6, pages 403-415, teach the *Agrobacterium Rhizogenes* transformation of tomato and soybean (p. 409, Table 2) to produce transformed roots.

Savka et. al. (1990) *Phytopathology* vol 80, pages 503-508, teach that *Agrobacterium Rhizogenes* K599 is "by far the most effective in inducing hairy roots in soybean" (p. 506 ¶ bridging to p. 507).

It would have been obvious to one skilled in the art to apply Tulson et. al, to other dicot plants, such as cotton, given the knowledge that dicot plants are known to be susceptible to *Agrobacterium Rhizogenes*, without any surprising or unexpected results. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Art Unit: 1638

Given the knowledge that tomato and soybean are readily transformed by *Agrobacterium Rhizogenes* to produce transgenic roots as taught by Simpson et. al., and that *Agrobacterium Rhizogenes* strain K599 is exceedingly effective at producing transgenic roots on soybean, one skilled in the art would have been motivated to substitute for the cucumber of Tulson, the soybean and tomato of Simpson et. al., or cotton, to produce transgenic roots, and to utilize *Agrobacterium Rhizogenes* strain K599 of Savka et. al., for its known effectiveness on soybean, to produce transgenic soybean, cotton and tomato root cultures. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary. Accordingly, the claimed invention is prima facie obvious in view of the prior art

Remarks

13. No claim is allowed.

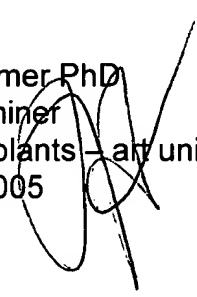
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on M-Th, 10:30 AM-6:30 PM.

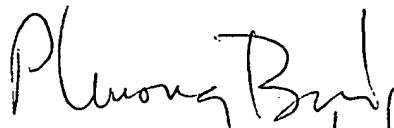
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Transgenic plants - art unit 1638
2 October 2005




PHUONG T. BUI
PRIMARY EXAMINER 10/3/05